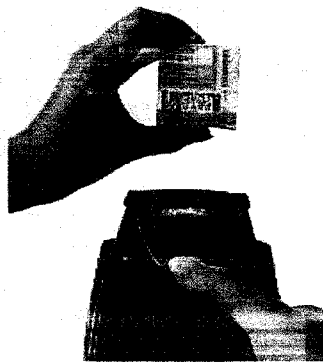


6/20/02 AUG -2 P2:18

The Business Case
for
REDUCING DRUG ADMINISTRATION ERRORS
USING 2D BARCODES



Prepared by

Mike Sim
Chief Executive Officer
Advias (Advanced Information Assurance Solutions Inc)
Project Office: Suite 700 North Tower
7799 Leesburg Pike
Falls Church, VA 22043-2499

25 July 2002

02N-0204

TS 7



THE BUSINESS CASE FOR REDUCING DRUG ADMINISTRATION ERRORS USING 2D BARCODES

1.	BACKGROUND	3
	Industry Supply Chain	3
	Hospital Pharmacy Process	3
	Ward and Outpatient Departments.....	3
	Clinical Trials Drug Administration and Audit.....	3
	The Link.....	3
	Improving the Link	4
2.	SYSTEM BENEFITS.....	5
3.	THE NEXT STEP	5

The views expressed in this document reflect those of Advias Inc and are not intended to reflect those of any official government directive or legislation. Nor does it reflect those of any barcode scanner manufacturer.



THE BUSINESS CASE FOR REDUCING DRUG ADMINISTRATION ERRORS USING 2D BARCODES

1. BACKGROUND

The long-term management of prescribeable drugs has always presented hospital pharmacists, doctors and nurses with particular challenges. Like the retail environment there are many elements and links in the hospital process that can adversely affect the safe delivery and audit of those drugs and their administration. Significant numbers of adverse effects and deaths have occurred due to human errors which happen all too frequently. Adverse events resulting from recalled drugs are virtually impossible to associate correctly. Therefore a true reflection of the magnitude of this process is unquantifiable at this time. These elements and processes are linked together by:

Industry Supply Chain

- a) Pharmaceutical company manufacture and distribution which includes batch number and expiry date information on the majority of packages. This information is not in machine readable format and therefore not readily easy to incorporate in any end-user system
- b) Pharmaceutical wholesaler supplying hospitals and clinics receive the products in the same format

Hospital Pharmacy Process

- a) Standard packaging with or without ID barcodes which only gives look up information
- b) Re-packaging to useable ward or patient size containers
- c) Clinical trials materials in non standard packaging format
- d) Dispensing from doctor order entry which still includes hand written as well as electronic ordering
- e) Delivery to ward, OPD or another hospital by ancillary staff

Ward and Outpatient Departments

- a) Patient identification and authentication using a variety of identification systems. These include 1D barcodes on wrist bracelets
- b) Administration of drugs at ward or clinic level
- c) Receipt of drugs issued to patients
- d) Return or disposal of unused drugs

Clinical Trials Drug Administration and Audit

- a) Protocol authority for inclusion in trial
- b) 2-way issue, administration and return of unused product

All the processes listed above could apply to a single patient. This means that there are many links in the system where the chain of custody could be broken. What is needed is a process that has the ability to link all the above with the assurance that all the information can be recorded and retrieved for validation and audit both at a local level and at government level for national epidemiology tracking

The Link

The common useable link in any pharmacy, hospital or community is the 1D barcode that is applied at manufacture. This 1D barcode is pre-printed onto the packaging material as a

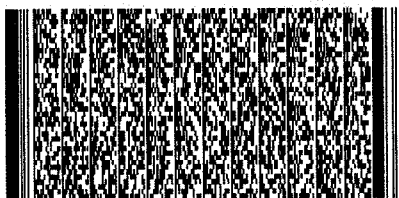


general identifier. The Pharmaceutical Industry undertook to mark all distributed products in this way. At this time that barcode is limited to a 1D barcode containing a link to:

- a) Drug name (generic/trade)
- b) Drug dose
- c) Unit size

Improving the Link

A number of symbology companies have now developed more complex 2D barcodes which can store a significant amount of information in the printed format. In the early 90s Symbol Technologies developed a 2D barcode called PDF417. This allowed the storage of about 1100 bytes of data in a single machine-readable barcode using standard industry 2D scanners. PDF stands for "Portable data file" with no need to link to reference information. This is now widely used throughout the world and is currently the storage mechanism on more than 80 million ID cards and hundreds of millions of documents. Logistic companies in the collection and delivery of packages use a variety of 2D barcodes every day. PDF417 2D barcode is now accepted as the de facto data storage media for US driving licences, US Postal Services and internationally in healthcare on prescriptions for the Spanish National Health Service. There are now a number of different symbology companies producing a variety of scanners which can read multiple variations of 2D barcodes.



PDF417

Public domain 2D barcode developed by Symbol Technologies. This machine-readable barcode can store up to 1100 bytes of data which can be emailed and printed on multiple surfaces.

In the late 90s Symbol Technologies developed a variation on PDF417 with micro PDF (known as reduced space symbology). This was designed to hold 90 characters and is small enough to be used in healthcare where it can be printed to sit on the side of a glass ampoule and on foil strips of drugs. The key advantages with this format are that the following information and more can be instantly scanned in from the drug without reference to a database. They are: -

- a) Drug name
- b) Drug strength
- c) Pack size
- d) Date of manufacture
- e) Batch no
- f) Expiry date
- g) Allergy warnings



RSS

Micro PDF, known as "Reduced space symbology". Holds up to 90 characters of ASCII text. Designed for use by the pharmaceutical and computer industry.

This means that for the first time it is possible to label drugs in the system with this information and, by means of a micro PDF barcode, link the drug from initial delivery through treatment and, if needed, returned stock to the pharmaceutical company (i.e. clinical trial). This linkage to patients would be via PDF417 barcode on their wrist bracelets or printed in PDF417 barcode format on their medical or prescription records. The process ideally should



be applied at manufacture. It could however be part of the internal pharmacy labelling process, particularly where they want to purchase large containers and repackage to a convenient size.

This process has already been applied in Europe to veterinary medicine with Vettrac™, which is a track and trace process for animals in the food chain. In this system all the drugs dispensed are automatically matched to the recipient with the resulting information uploaded to the animal's individual medical history. The process also generates accounts to be sent to farmers. Veterinary pharmaceutical wholesalers in Europe are labelling the drugs themselves with micro PDF to facilitate this use of the technology. The eventual aim of the veterinary world is to persuade the Pharmaceutical Industry to apply the micro PDF during manufacture. These veterinary pharmaceutical manufacturers are the same companies that supply the US healthcare industry.

2. SYSTEM BENEFITS

The process would operate via the hospital computer network. This would allow analysis of information that would include: -

- a) Detailed stock record displayed instantly at any authorised PC
- b) Instant audit of where every package is located
 - i. Pharmacy
 - ii. Internal delivery
 - (i) Satellite pharmacy
 - (ii) Ward
 - (iii) Detailed information on all drugs issued to any named patient
 - (iv) Returned to pharmaceutical company
- c) Ability to scan and identify faulty or withdrawn drug without blindly checking all boxes in circulation
- d) Identify and use products in delivery date order, thus avoiding the data expiry of drugs with the subsequent cost implications associated with unusable drugs or drugs stored beyond their active safe shelf life.
- e) In addition to the micro PDF barcode identifiers Advias has now developed a process that stores facial recognition templates and photo ID alongside text information on the patient's wrist ID, patient notes and staff ID in PDF417. This gives the patient ownership and control of their facial biometric when linked to the drug identification process they can jointly aid error reduction.
- f) The process can be used with either tethered scanners or ported to PDA (with 2D scanner) operated either as a batch device or communicated live using 802.11b wireless.

3. THE NEXT STEP

Advias is now in discussion to trial this 2D barcode process in a leading US hospital. The key requirement of this trial is to demonstrate quantifiable reduction in drug errors. This trial will also provide data on the other less obvious benefits of using this scanning technology.

Further information is available from info@adviasinc.com